EXHIBIT F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-02327
	:	MDL NO. 2327
MARY K. WARD, et al	:	
v.	:	CASE NO. 2:12-cv-02198
ETHICON, INC., et al.	:	

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August 11, 2016

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Expert deposition of KONSTANTIN WALMSLEY, M.D., taken pursuant to notice, was held at Courtyard Marriott West Orange, 8 Rooney Circle, West Orange, New Jersey, beginning at 9:03 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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(Deposition Exhibit No. Walmsley (Ward)-1, Notice of Deposition of Konstantin Walmsley, M.D., was marked for identification.)

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(Deposition Exhibit No. Walmsley (Ward)-2, Rule 26 Expert Report of Konstantin Walmsley, M.D., was marked for identification.)

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(Deposition Exhibit No. Walmsley (Ward)-3, 11/20/15 Curriculum Vitae of Konstantin Walmsley, was marked for identification.)

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(Deposition Exhibit No. Walmsley (Ward)-4, Document Titled "Materials Reviewed", was marked for identification.)

- - -

(Deposition Exhibit No. Walmsley (Ward)-5, 6/17/16 Encounter Summary for Mary Ward, was marked for identification.)

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(Deposition Exhibit No. Walmsley (Ward)-6, Transcript of the 7/28/16 Deposition of Geoffrey DeLeary, M.D., was marked for identification.)

- - -

(Deposition Exhibit No. Walmsley (Ward)-7, Draft Transcript of the 8/8/16 Deposition of Robert Highland, M.D., was marked for identification.)

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KONSTANTIN WALMSLEY, M.D., after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MS. ROBINSON:

Q. Doctor, will you please state your full name for the record?

A. Konstantin Walmsley.

Q. You understand that you're under oath and you've sworn to tell the truth here today just as if you were sitting in a court of law; is that correct?

A. Yes, ma'am.

Q. Doctor, you have been hired by the Motley Rice firm in the case involving Ms. Mary Ward; is that correct?

A. That's correct.

Q. And she was implanted with the TVT mid-urethral sling device in June of 2005; correct?

A. Yes.

Q. And that is an Ethicon product; correct?

A. Yes.

Q. What were you asked to do specifically with regard to Mrs. Ward's case?

A. I was asked to review medical records relating to her care. In addition, I was asked to perform an independent medical examination of this patient, and I was also asked to generate a report based on my findings.

Q. And did you do that?

A. Yes, I did.

Q. When were you first contacted by Motley Rice?

A. Originally, in early April.

Q. Early April and in 2016?

A. When you say contacted by Motley Rice, are you regarding -- are you talking about Mrs. Ward specifically or about other work?

Q. That's a good question. So with regard to Mrs. Ward specifically, when were you first contacted by Motley Rice?

A. That was probably more in the late May to early June scenario, somewhere around there.

Q. And you say, sometime in

April, you were first contacted. Were you first contacted by Motley Rice to offer opinions involving mesh litigation?

A. That's the first time they asked me to provide opinions regarding Ethicon-based mesh litigation.

Q. Have you offered opinions for Motley Rice in cases involving other mesh products?

A. I have not.

Q. So has your testimony been limited only to -- so far, has your testimony been limited only to Ethicon products?

A. With regards to Motley Rice, yes, that's true.

Q. And have you offered expert services for any other law firms suing companies that manufacture mesh?

MS. SANTRA: I'm going to object to the form as this is general in nature and we're here for the case-specific opinions on Ms. Ward.

THE WITNESS: Should I answer the question?

MS. ROBINSON: Yes --

MS. SANTRA: You can answer.

MS. ROBINSON: -- go ahead and answer the question, Doctor.

THE WITNESS: I'm sorry. Yes.

BY MS. ROBINSON:

Q. And what other products have you offered expert testimony about, mesh-related products?

MS. SANTRA: Object to the form.

THE WITNESS: Bard, Bard Avaulta, and Bard Align TO; Boston Scientific, I believe the Uphold device, the AMS Elevate device --

BY MS. ROBINSON:

Q. Any others?

A. As I sit here today, I don't recall any others.

Q. When did you first start consulting as an expert in mesh

litigation overall?

MS. SANTRA: I object to the form. Susan, does this have anything to do with Ms. Ward? I'm going to have to at some point instruct him not to answer.

MS. ROBINSON: Can he answer that question?

MS. SANTRA: Sure.

THE WITNESS: I believe roughly around 2013.

BY MS. ROBINSON:

Q. Doctor, part of my reason for asking this question is because in the past and currently, I've never been provided with a list of the testimony that you have provided in your cases, and I keep trying to get counsel to provide me with that list, but I don't have it.

Have you ever prepared a list of the testimony that you have given in the last four years?

A. Yes.

Q. Have you provided that list

to Motley Rice?

A. Yes.

Q. Do you know why it was not produced to me as a part of Mrs. Ward's report?

MS. SANTRA: I object to the form. Susan, I can get that for you today.

MS. ROBINSON: Okay. If you can e-mail that to me while we're doing the deposition, that would be great.

MS. SANTRA: Okay. I'll have to...

BY MS. ROBINSON:

Q. So, Doctor, Exhibit No. 1 in front of you is your Notice of Deposition; correct?

A. Yes.

Q. And that's a familiar form to you; is that correct?

A. Yes.

Q. And it requests that you bring certain documents and records to

the deposition. Did you bring anything with you today?

A. The only thing I brought with me today was my computer on which I have most of the document requests you've asked for in this form.

Q. Other than the medical records that are listed on -- let me go ahead and your -- Exhibit No. 2 in front of you should be your report; is that correct?

A. Yes.

Q. And on page 2 of your report, it continues onto page 3, there is a list of medical records you reviewed in Mary Ward's case.

Do you see that?

A. Yes.

Q. Other than those medical records, have you reviewed any other materials in preparation for her -- I'm sorry. Strike that. Let me reask that question.

Other than these medical

records, have you reviewed any other medical records that you utilized to formulate your opinions in Ms. Ward's case?

A. I have reviewed some additional medical records that were provided to me by counsel.

Q. And what medical records would these additional records be?

MS. SANTRA: I can -- I can send you a link to the records we've sent Dr. Walmsley, if that is helpful.

MS. ROBINSON: When you say "link," what are you referring to?

MS. SANTRA: A share file link to the -- all the records that we have sent Dr. Walmsley.

MS. ROBINSON: Okay.

BY MS. ROBINSON:

Q. And, Doctor, were -- these additional records that you're talking about today, were they received after you wrote your report and formulated your

opinions?

A. Yes.

Q. Did those medical records that you reviewed after writing your report change your opinions in any respect?

A. No.

Q. Now, on page 3 of your report, it lists that you reviewed the depositions of Mary Ward and Jeffrey Ward; correct?

A. Yes.

Q. Since writing your report and formulating your opinions in this case, have you reviewed any other deposition testimony?

A. Yes.

Q. Have you reviewed the deposition testimony of Dr. DeLeary?

A. Yes.

Q. And you understand he was her -- the physician that implanted the TVT device; correct?

A. Yes.

Q. Did anything that you read in Dr. DeLeary's deposition alter your opinions in any way?

A. No, ma'am.

Q. Did anything you read in Dr. DeLeary's deposition strengthen or weaken your opinions in any way?

MS. SANTRA: Object to form.

THE WITNESS: No, not especially.

BY MS. ROBINSON:

Q. When you say "not especially," is there anything in particular you have in mind when you make that qualification?

A. Well, it was a little bit of a broad question insofar as I'm thinking of elements that were weakening or elements that were strengthening; and I definitely didn't find any elements that would weaken it, but as I sit here today and think about the other part of that question, I don't specifically remember any elements of that deposition that

would have, let's say, galvanized a particular opinion I put forth in my report.

Q. Okay.

With regard to Dr. Highland, have you had the opportunity to review his transcript?

A. Yes.

Q. Did the deposition testimony of Dr. Highland change or alter your opinions in any way?

A. Not especially, no.

Q. And when you say "not especially," again, what do you mean by that qualification?

A. There weren't any particular findings or passage in his deposition that would lead me to say, to a significant degree, well, maybe this calls to question my opinion in my report.

And the flip-side is true. There was nothing in his deposition that would otherwise have gone the other way

around there.

Q. Have you read any other deposition testimony --

A. I have not.

Q. Have you seen the expert report of Dr. Matthews?

A. Yes.

Q. You did not file a rebuttal to her expert report; is that correct?

A. That's correct.

Q. Other than, obviously, you and Dr. Matthews disagree as to ultimate opinions, was there anything in Dr. Matthews' report that caused you specific concern?

MS. SANTRA: Object to form.

THE WITNESS: No.

BY MS. ROBINSON:

Q. Exhibit 2, which is your final report, does it contain all of your opinions and the basis for those opinions that you intend to give in this case?

A. Yes.

Q. Now, Exhibit No. 4 in front

of you has been identified as your reliance materials. Can you describe for me just in general what that material is?

A. Yes. So it's a three-page document listing materials reviewed, in part depositions of medical providers and also depositions of patients and perhaps their spouses, instructions for use, the plaintiff fact sheet, incorporated materials, and then also about a two-and-a-half-page list of medical literature.

Q. Is there any specific medical literature that you have identified on Exhibit No. 4 that you relied upon in Mrs. Ward's case?

MS. SANTRA: Object to form.

THE WITNESS: Well, I mean, I really relied upon the whole body of work, so -- I mean, if you're asking me is there one particular article that is by far and away the one standout article that I think strengthens Mrs.

Ward's report, it would be hard for me to identify just one article.

BY MS. ROBINSON:

Q. Okay.

And another part of that question I would ask you is whether there is any one particular complaint or injury that Mrs. Ward suffered that, in the review of your material, that you relied more upon one particular literature than another?

MS. SANTRA: Object to form.

THE WITNESS: That's a bit of a challenging question only because I've never kind of had a question like that posed to me in that fashion.

And it's very hard for me as I sit here today to point to one or two articles that would necessarily correlate with the one particular symptom that I would pick out as being the most

compelling symptom based on the literature.

And the reason I say that is because, I mean, generally speaking, as it relates to Mrs. Ward, she has pelvic pain. She has dyspareunia and she has voiding dysfunction.

And the articles in my reliance list, some of them focus on mesh retraction. Some of them focus on clinical complications. Some of them focus on mesh-specific properties such as retraction and such.

So it's difficult for me to, first off, point to one particular complaint she has that I think is the most compelling complaint and then, second off, you know, identify one, two, or three articles that speak to that particular complaint, because they all kind of interweave as I form

my opinions.

BY MS. ROBINSON:

Q. Doctor, when was mesh retraction or contracture first reported on in the medical literature?

MS. SANTRA: Object to form. This goes to general opinion.

THE WITNESS: Well, that's a very difficult question to answer, because with regard to my references, for example, many of my references that discuss mesh retraction date to a period of time after 2009-2010.

That being said, I'm sure if I was put to task, I could find articles that go back to prior times that describe mesh contraction.

BY MS. ROBINSON:

Q. Doctor, are you aware of any literature that describes mesh retraction as early as the 1980s?

A. As we sit here today, I am

not aware of that.

Q. Are you aware of any scientific literature that reports upon mesh retraction as early as the 1990s?

MS. SANTRA: Object to form. This is general again.

MS. ROBINSON: Well, I'm specifically asking you about your reliance list and the material you relied upon for Mrs. Ward's case, and I believe that --

MS. SANTRA: You're asking a very general question about what literature came out in 1990.

MS. ROBINSON: You know, there is no real prohibition about me asking him general questions. I mean, the prohibition is about me going over material that he's testified to ad nauseam on multiple occasions. I don't and haven't seen where he's testified about this material.

So your objection, while I

appreciate it, isn't -- you know, just because it's a general question doesn't mean it's prohibited.

And, Doctor, I'm asking you specifically whether physicians who were implanting mesh as of 2005 would have known that mesh retraction and contracture was reported in the medical literature.

MS. SANTRA: Object to form.

You can answer.

THE WITNESS: That's obviously a different question insofar as now we're dealing with a different time period; correct?

MS. ROBINSON: Well, yeah, but that's essentially what I'm getting at. Okay?

BY MS. ROBINSON:

Q. And so let's step back again and let me ask the question.

In the years of -- in the

1990s, was mesh retraction reported in the medical literature?

MS. SANTRA: Object to form.

THE WITNESS: You know, in the 1990s, I was finishing medical school and just about to, you know, start my urology residency. So certainly realtime back then, it was not something I faced or dealt with in clinical practice and, you know, when I first started using pelvic mesh for the management of stress urinary incontinence, which was in 2000-2001, my knowledge of mesh retraction currently -- I mean, it existed back then. It existed primarily because my teaching implanting surgeons and even key opinion leaders who were at some of the sling workshops I attended described that there was a mesh contraction process of about 10 to 20 percent depending upon the

sling used.

So I don't know if that answers your question as it relates to is there medical literature speaking to that, but it was certainly common knowledge to me in my training that this was a phenomenon that not only existed, but called for us to use tension-free placement.

BY MS. ROBINSON:

Q. And you're a urologist; correct?

A. Yes, ma'am.

Q. And your training was as a urologist; correct?

A. With an additional year of fellowship training that was female urology-specific, yes.

Q. And do you have any reason to believe that other urologists who were performing stress urinary incontinence surgical procedures would not have been aware of the fact that there was mesh

contracture and retraction in the year 2005?

MS. SANTRA: Object to form.

THE WITNESS: Well, I mean, I can only speak for myself. This was my breadth of education and experience. You know, perhaps there were other urologists that looked at different medical literature or had a different basis of understanding, but it was understood to me in that fashion.

BY MS. ROBINSON:

Q. And that the contracture could be up to 20 percent?

A. Yeah, the description was anywhere from 10 to 20 percent contraction. That was really, to my understanding, multifactorial. It wasn't simply just the actual mesh itself contracting. It wasn't the fact that the polypropylene wasn't inert, but it also related to wound healing and wound contraction, which can cause a shrinkage

effect as well.

Q. And has your understanding about that changed in any respect up to today?

A. To some extent, yes.

Q. In what way?

A. In that I didn't correlate, at least not back in 2005, the mesh retraction properties and their effects on things such as vaginal pain.

Q. And is that the only way?

A. Also with overactive bladder symptoms. It wasn't just pain, per se. It was voiding dysfunction.

Q. Were you aware in 2000 and -- 2000 and 2001 and 2005 that such things as pain and voiding dysfunction could be associated with the placement of a TVT?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. And so what you're telling me is that you had not fully appreciated

the mechanism of the mesh through the contracture or retraction vis-a-vis the pain and the overactive bladder; is that what you're saying?

MS. SANTRA: Object to form.

THE WITNESS: I guess -- yeah, I guess what I'm saying -- and perhaps this is the same way of saying it in different words -- is that inasmuch as I was aware of the properties of mesh retraction, I wasn't necessarily aware that that particular process led to end results, some of those end results being pain and voiding dysfunction.

BY MS. ROBINSON:

Q. But you were also aware -- while you were not specifically aware of the properties, you were, in fact, aware of the end result could be the risk of implanting TVT would be pain as well as voiding dysfunction; correct?

MS. SANTRA: Object to form.

THE WITNESS: That was an understanding of that surgery at that time, that's correct.

BY MS. ROBINSON:

Q. So, Doctor, your C.V. is in front of you and it's marked as Exhibit No. 3?

A. Yes.

Q. And I believe it's dated as of November of 2015. Do you have a more recent C.V.?

A. I actually do have one that I don't believe I've actually submitted as yet, but I recently updated it, not on the basis of my urological practice, but on the basis of some of my extracurricular activities.

MS. ROBINSON: And, Hayleigh, I would request a copy of his updated C.V.

THE WITNESS: I can do that.

MS. SANTRA: Sure.

BY MS. ROBINSON:

Q. Doctor, between the time

period of November of 2015 up until today, have you written any articles regarding stress urinary incontinence?

A. No.

Q. Have you written any articles regarding mesh?

A. No.

Q. Or polypropylene.

A. No.

Q. Have you written any articles on pelvic floor dysfunction whatsoever in that time period?

A. No.

Q. Are there any -- other than you said some of your activities, are there any other substantive materials or work that you would have done between November 2015 and today that reflect on your expertise here testifying as a urologist in a stress urinary incontinence case?

A. No.

Q. Is your fee still $500 an hour for the work you perform?

A. Yes.

Q. Have you submitted any invoices in Mrs. Ward's case?

A. I have.

MS. ROBINSON: Hayleigh, can I get a copy of the invoices that have been submitted?

MS. SANTRA: Yes.

BY MS. ROBINSON:

Q. Can you give me an estimate of how much time you've spent overall in Mrs. Ward's case to date?

A. Yes, I can. I spent roughly eight hours reviewing the initial salvo of medical records and another roughly three hours preparing the report; and then in terms of my additional review for this deposition, I've spent roughly an additional three hours reviewing some additional medical records, depositions, and then Dr. Matthews' expert report.

Q. How long did the IME take?

A. Roughly 45 minutes.

Q. And I understand that you

bill through your practice for that?

A. My practice bills for that service, that's correct.

Q. Approximately how much does that service cost?

A. $350.

Q. Do you anticipate spending any more time on Mrs. Ward's case until such time as it may be set for trial?

A. Possibly in terms of reviewing the deposition. That would be the only additional work at this point I could envision.

Q. And that's your own deposition you're talking about. Right?

A. Yes, ma'am.

Q. Doctor, let's turn to Exhibit No. 5, please.

A. (Witness complies.)

Q. That's your medical examination of Mrs. Ward; is that correct?

A. Yes, ma'am.

Q. And that is a five-page

document?

A. Yes.

Q. Did Mrs. Ward fill out any patient questionnaires before her examination by you?

A. No.

Q. Did you make any handwritten notes either of your review of her medical records prior to writing your report or during her medical examination?

A. I did not.

Q. Did Mrs. Ward bring any documentation to her appointment with you, either things like voiding diaries, her medical records, anything of that nature?

A. No.

Q. You examined her in your office in New Jersey; is that correct?

A. Yes.

Q. She did not make any complaints to you of having any difficulty due to any physical limitations or pain in traveling to North

Carolina -- or from North Carolina to be examined by you; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: I don't specifically recall such.

BY MS. ROBINSON:

Q. If she had made any such complaints and they were relevant to her mesh litigation, that's something you would have noted in your medical exam report; is that correct?

A. I would think so, yes.

Q. Before you saw her for your medical examination, what material had you reviewed in her case?

A. Nothing.

Q. You had not reviewed any of her medical records before June 17th of 2016?

A. Generally speaking, what I like to try to do -- I don't do this with every patient, but I almost would prefer to see them and perform the IME in the absence of any medical records just so I

could have a more innocent, if you will, blank slate kind of opinion of the patient.

Q. And you have a specific recollection in this case you didn't review anything before her examination.

A. I don't specifically recollect reviewing records before this particular individual, no.

Q. Can you tell me how the examination is conducted? What happens first and so forth?

A. Certainly. So the patient comes to the office. There is an inventory or intake of the patient performed by my medical assistant. During that time, the patient's pharmacy information is taken, the medications they're taking are recorded, vital signs are measured, the past medical and past surgical history is noted in the electronic health record.

There is inventory of social history, family history, and review of

systems that's provided by my medical assistant, and then the urine analysis is also -- the dipstick, that is, is -- that data is entered.

Once that's done, the patient comes back to an examination room and then I will come in and interview the patient. During the interview, I, generally speaking, document and record as much information as possible and certainly the information that I feel is relevant.

After the interview is completed and all the questions have been asked, I step out of the room, have the patient change, come back and perform a chaperoned examination of the patient that's documented and, in certain instances, will also check the -- what's called the postvoid residual of that patient, in other words, how much urine is left behind in their bladder after they pee.

Following the physical

examination having been performed, I then complete the independent medical record with an assessment and, if applicable, a plan.

Q. You say, "if applicable, a plan."

A. Correct.

Q. What do you mean by that?

A. Well, in a lot of instances, when I see patients such as Mrs. Ward, I'm not necessarily their treating physician, so I don't necessarily actively manage the problems they pose to me.

Q. So the plan would be if you have -- in the ordinary course of your work, if you're seeing a patient that you're treating, a plan would be what are the next steps essentially.

A. That's correct.

Q. Could that plan include follow-up testing in order to confirm your preliminary diagnosis?

A. In certain instances.

Q. And with regard to patients that you're seeing as an expert, are -- do you formulate such a plan for them?

A. Usually not.

Q. So in Mrs. Ward's case, would there be any follow-up testing that you would recommend, that you did not recommend, if she had been your patient?

MS. SANTRA: Object to form.

THE WITNESS: Not necessarily.

BY MS. ROBINSON:

Q. And what's the qualification you have on that?

A. Well, I mean, certainly gaining more information on a patient can be helpful in certain instances. So, you know, for example, if a treating physician taking care of Mrs. Ward decided to, let's say, order a urodynamics test or perform cystoscopy or recommend that, I wouldn't necessarily fault the physician for ordering that type of test or evaluation.

As it relates to me, I'm not sure if either of those two tests as an example would have led to either a change in my opinion or, if I was actively treating the patient, a change in my plan of treating her.

So speaking for my own personal instance as a treating physician, which I'm not in this case, if you're asking me if I would have ordered those types of tests or any additional tests, I probably would not have.

Q. Are there any tests that if you were a treating physician that you would have ordered for her?

MS. SANTRA: Object to form.

THE WITNESS: Not right away, but possibly, yes.

BY MS. ROBINSON:

Q. And what possibly would you have ordered later?

A. I might have found, for example, in her, a urodynamics test to be helpful.

Q. And for what reason?

A. Well, one thing interesting about Mrs. Ward is, she has fairly severe incontinence and it's mixed incontinence. She describes having urinary urgency incontinence, but also stress incontinence.

If conservative measures at treating her incontinence were not to work, a urodynamics test might help explain the real nature of her voiding dysfunction as far as, for example, which type of incontinence predominates.

Q. You indicated she has severe incontinence. How do you classify her current complaints of incontinence as severe?

A. So her incontinence is severe to my mind on two findings, on two bases: First off, it's a significant quality of life bother for her. Second off, it's different and worse, in fact, than it was prior to her sling surgery by account of the patient.

Q. And when you say different and worse by account of the patient, you're saying, is that based solely upon her description of her current complaints?

A. Well, I guess it's about her description and her relating that to me and my documentation of such. I mean, she told it to me in our IME that it was worse and I believe she also stated that in her deposition.

Q. But you have not done any testing that would -- well, strike that. Let me ask this question.

A. Sure.

Q. She had a cystoscopy prior to her sling procedure in 2005; is that correct?

A. Yes, she did.

Q. Did she have urodynamics at that time as well?

A. Yes, she did.

Q. If you had performed those two tests, is there any way in comparing

those two tests that you would be able to make an objective determination as to whether her problems today are different or worse than they were in 2005?

A. I think it's possible to do that, yes.

Q. But that has not been done; correct?

MS. SANTRA: Object to form.

THE WITNESS: Not by me, it has not.

BY MS. ROBINSON:

Q. And how is it possible? Can you please describe for me what might be shown today if you were to perform those two tests?

A. Well, obviously it's very hard for me to know that since they've not been done, but I mean, the way those tests, if they were performed today, could possibly be helpful is if they showed different findings from what was seen in 2005.

Q. And those findings could

relate to showing you whether at this point in time her overactive bladder symptoms are worse today than what they were in 2005; is that correct? Is that one way?

MS. SANTRA: Object to form.

THE WITNESS: I think they could help, but, you know, urodynamics tests are a little bit challenging because we're asking -- what we're trying to do is essentially recapitulate normal bladder function in patients who are essentially sitting on a commode.

The only issue is, they're sitting on a commode with catheters in their urethras and recti. They have patches on them. They're being visualized, so it can provide a lot of helpful information.

But there are nuances to doing the procedure that sometimes

make the kind of comparison or differentiation you're speaking of somewhat more difficult to put forth.

BY MS. ROBINSON:

Q. Okay. Let's go back to Exhibit No. 5, please. Do I understand then in looking at this report that everything up to the HPI was information that the patient provided to your assistant?

A. Yes, with the exception of medications. The medications are automatically populated because of electronic reviews of pharmacy prescribing, so the medications are auto-populated, but everything else is provided by my medical assistant.

Q. And who was your medical assistant in this case?

A. Quite frankly, I don't remember who it was. It was one of three people.

Q. When you look at page 1 of

this report, under US, bladder, does that reflect that an ultrasound was performed of her bladder?

A. Yes.

Q. And that's something that you performed yourself?

A. Yes.

Q. Did you do that after she had voided?

A. Yes.

Q. How long after she had voided?

A. Probably within about 15 minutes.

Q. And her postvoid residual is 15 milliliters; is that correct?

A. Yes.

Q. What does that show?

A. That shows that she empties her bladder fairly well, very well.

Q. I'm sorry? I missed that last part.

A. It indicates that she empties her bladder very well.

Q. And does that indicate to you that she does not have any obstruction of her bladder or urethra?

A. Not necessarily.

Q. Can you explain that to me?

A. Yes. So postvoid residual can be really a reflection of two different phenomena, one being the degree of obstruction or restriction at the level of the bladder outlet. The other can be a reflection of bladder strength, the muscular strength of the bladder that allows the bladder to push fluid out.

Q. So with regard to obstruction of the bladder outlet, is that something that -- well, let me just ask it this way: Based on your examination of Mrs. Ward, does she have obstruction of her urethra?

A. It's hard to answer that question. I think it's possible.

Q. But you're not able to testify to a reasonable degree of medical certainty that Mrs. Ward's urethra is

obstructed by the TVT; is that correct?

A. I would agree with that.

Q. With regard to her bladder strength, are you able to say that -- well, what does this test tell you with regard to her bladder strength, if anything?

A. Well, it certainly indicates to me that her bladder is not underactive.

Q. Does it tell you anything as to whether her bladder is overactive, the postvoid residual test?

A. It can be part -- it can be part of the data needed to confirm that, yes.

Q. And does this amount of postvoid residual show any indication that she has overactive bladder?

A. It's supportive of that.

Q. How is it supportive of that?

A. When I come across a patient who has symptoms and/or signs of

overactive bladder, for example, urgency urinary incontinence, certainly seeing urgency urinary incontinence in someone who has a low postvoid residual as opposed to a high postvoid residual is more supportive and reflective of an overactive bladder condition in the proper clinical context.

Q. Is there anything else that her postvoid residual -- any other information that you gained from that with regard to your diagnosis of her?

A. Yes. To some degree, yes.

Q. What else?

A. She does have a history of recurrent urinary tract infections; and on occasion, recurrent urinary tract infections can occur in patients who don't empty their bladder completely.

The fact that her postvoid residual was low on this visit reflects to me that that pathophysiology, if you will, is probably not relevant here.

Q. Under her problem review, is

this information that the plaintiff, Mrs. Ward, told your medical assistant?

A. We're speaking about reviewed problems on page 1?

Q. Yes.

A. Those are populated kind of retrospectively, if you will, once the assessment is populated. So the reviewed problems are simply a reflection -- reflections of what's provided in the assessment diagnoses, which are the last two pages.

Q. Okay. Is that something then that you would populate?

A. That's correct.

Q. And one of the things reflected here is constipation; correct?

A. Yes.

Q. You agree with me that constipation has been a complaint of Mrs. Ward's for some time period.

A. Yes.

Q. Including before her surgery with TVT in 2005; correct?

A. Yes.

Q. And -- okay. Do you -- well, you are not testifying that TVT has anything to do with her constipation; correct?

A. No. That's correct.

Q. Do you agree with me that constipation can cause pelvic pain?

A. Depending upon its severity, yes.

Q. Do you agree with me that the pelvic pain that can be caused by constipation can be intermittent?

A. Yes.

Q. Do you agree that pelvic pain that can be caused by constipation can occur on and off over a number of years?

MS. SANTRA: Object to form.

THE WITNESS: I think, depending upon its severity, that could happen.

BY MS. ROBINSON:

Q. Chronic cystitis is listed

as well. Do you see that?

A. Yes.

Q. What is that intended to represent here?

A. That's intended to be reflective of the fact that this patient's had recurrent urinary tract infections.

Q. You do not relate that to her TVT; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: I -- actually, I do.

BY MS. ROBINSON:

Q. Okay. Well, Doctor, I'm not prepared to ask you questions about her UTIs today.

A. Okay.

Q. And one of the reasons I'm not going to do that is, nowhere in your expert report do you say that her urinary tract infection complaints are caused by the TVT.

Do you agree with me on

that?

A. I do.

Q. And I'm not going to ask you those questions. Okay?

A. Okay.

Q. Dyspareunia, do you see that?

A. Yes, I do.

Q. And that's something that you've added in there and we'll talk about that more later.

Pain in pelvis --

A. Yes.

Q. -- can you tell me what the basis is for her -- this entry? I mean, what's it based upon?

A. So when I examined her -- actually, I -- scratch that.

Before I examined her and I started interviewing about her pain, she described starting to have some pelvic pain in 2010. Some of that pelvic pain came as a result of intimacy. Sometimes the pain occurred when she was not

sexually active. Specifically, she described having groin pain in both groins, described as intermittent, dull, sometimes worse after walking.

As you know, she actually had her hysterectomy done in part because of her pelvic pain. That surgery was not helpful in resolving her pelvic pain.

Those are the bases for my providing that as a diagnosis.

Q. Did you see anywhere in her medical history where she had complaints of pelvic pain other than in relation to her hysterectomy?

A. Yes.

Q. Can you show me those entries in your report?

MS. SANTRA: Object to form.

THE WITNESS: Let me take a look.

(Pause.)

THE WITNESS: Could you reread that question to me, Ms. Robinson?

MS. ROBINSON: I'll probably rephrase it because I'm not sure exactly how I asked it.

THE WITNESS: Okay.

BY MS. ROBINSON:

Q. But in your report, do you identify any complaints that Mrs. Ward made to any of her medical providers of having pelvic pain other than the instance prior to her hysterectomy where she had reported a pelvic pain in her lower left quadrant, I believe?

A. Well, I mean, I think, to be fair, she had an underlying history of constipation, which you and I have agreed could be a source of pelvic pain -- am I -- is that -- am I answering your question to your satisfaction? I mean, is that -- because to be fair, she did have that as a problem before her sling was ever done.

Did she ever say, "I'm having pelvic pain from constipation"? She did not. But I guess I'm trying to

answer your question by saying, you're asking me if she had any reason to have pelvic pain prior to her sling and that's, for example, one instance that might explain why she might have had it beforehand.

Have I seen her say, "I have pelvic pain" or medical records indicating that prior to her sling? I have not seen that.

Q. Okay. And my question is actually more specific as to up to today.

A. Okay.

Q. So let's break this out a little bit.

One, you agree with me that constipation could be a source of her pelvic pain; correct?

A. Possibly.

Q. And you haven't been able to rule that out as a -- to a reasonable degree of medical certainty as a potential source; correct?

MS. SANTRA: Object to form.

THE WITNESS: I mean, it would be very low on my differential, but I wouldn't completely rule it out, no.

BY MS. ROBINSON:

Q. Do we agree that she had endometriosis?

A. She did -- she was diagnosed with endometritis.

Q. And you're making a distinction there between endometriosis and endometritis? Or am I just pronouncing that wrong?

A. It's just that when I think of endometriosis, I think of a condition where you can actually find depositions of endometrial tissue in the pelvis; and her diagnosis was, I believe, based on a cervical biopsy, so I don't believe there was any other tissues that were found to contain endometritis.

Q. Okay.

Do we agree, however, that that condition that she had can cause

pelvic pain?

A. Yes.

Q. And you cannot rule that out to a reasonable degree of medical certainty as a potential cause of some of her intermittent complaints of pelvic pain; correct?

A. Up until her hysterectomy, I cannot.

Q. And you also understand that she had ovarian cysts; correct?

A. That's correct.

Q. And you agree with me that ovarian cysts can cause pelvic pain; correct?

A. Yes.

Q. Are you able to rule out the ovarian cysts as a potential cause of her pelvic pain?

A. Not entirely, no.

Q. So then my next question is whether you have seen documented in her medical records at any time up until today complaints of pelvic pain that

could not be attributed to one of those three conditions, that being her constipation, her endometrial tissue, and ovarian cysts.

MS. SANTRA: Object to form.

THE WITNESS: Are we excluding my IME from your question?

MS. ROBINSON: Yes, because I'm just asking about documents in her medical records.

THE WITNESS: I'm just going to ask you to ask that question one more time, if you would, for me.

MS. ROBINSON: Can I have the court reporter read it back, please?

- - -

(The court reporter read the pertinent part of the record.)

- - -

MS. SANTRA: And I object to the form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. Can you show me where that is --

A. Well, one example of that may be with Dr. Highland's office visit which was in March of 2015 where she was noted to have granulation tissue --

Q. Okay. Did -- were there specific complaints of pelvic pain at that time that you know of?

A. Well, once again, I mean, there were intermittent complaints. I don't recall in March of 2015 there being pelvic pain and granulation tissue listed in the same evaluation.

Q. Okay. Is that the only -- is that the -- is that office visit the only other one that you have seen in her medical records?

MS. SANTRA: Object to form.

THE WITNESS: Well, you know, once again, I'm of the understanding -- and this is

obviously based on my discussions with Mrs. Ward -- where that her hysterectomy was done not only because of vaginal bleeding, but because of pelvic pain.

Other than what I've just presented to you and the fact that she's had some UTIs, some left-sided pain, I'm going back to 2008 now, I'm not identifying any specific pelvic pain issues in the medical records that I've received.

BY MS. ROBINSON:

Q. With regard to the March 23rd, 2015 visit with the granulated tissue --

A. Right.

Q. -- do you agree that that was not related to her TVT?

A. I don't have any evidence that it was.

Q. What do you believe the granulated tissue was caused by?

MS. SANTRA: Object to form.

THE WITNESS: Probably healing from the hysterectomy.

BY MS. ROBINSON:

Q. So, Doctor, the medication list -- well, I'm sorry. Let's go on.

You have mixed incontinence listed in the review of problems; correct? And I'm back at Exhibit 5, your examination here?

A. Yes.

Q. She had mixed incontinence prior to her TVT; correct?

A. It was really almost purely stress incontinence as a matter of fact.

Q. But there were documented complaints in her medical records of overactive bladder symptoms as well, is that correct, by Dr. DeLeary?

A. Well, when she saw Dr. Highland -- she did have urodynamics done a few years prior seeing Dr. DeLeary where a diagnosis of mixed urinary incontinence was offered, and she also

used Ditropan XL, which is a drug used to treat overactive bladder.

That being said, when she saw Dr. DeLeary, you know, his impression was genuine stress urinary incontinence related to urethral hypermobility.

Q. And as you're sitting here right now, you don't recall seeing him make notations of some kind of overactive bladder.

A. What I recall is that he prescribed Enablex, but soon thereafter discontinued it when he operated on her, which suggests to me that he wasn't finding it or she wasn't finding it very effective.

Q. Now, TVT is indicated for the treatment of stress urinary incontinence; correct?

A. Yes.

Q. It is not indicated for the treatment of overactive bladder; correct?

A. Not directly, no.

Q. Some patients, however, who

do have overactive bladder along with stress urinary incontinence may see improvement of both by the use of TVT; is that correct?

A. That can happen sometimes, yes.

Q. And it very well could have happened with Mrs. Ward; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: It's possible.

BY MS. ROBINSON:

Q. And you understand that for an extensive time period, years, Mrs. Ward did see significant improvement of her urinary incontinence, is that correct, with the TVT?

A. She did have some improvement with her SUI, no question.

Q. And today, is it your impression that her mixed urinary incontinence is actually predominantly overactive bladder?

A. The impression I got from her was that it was about 50/50.

Q. What caused her SUI in 2005 before her TVT placement?

A. Well, anatomically, she had a condition called urethral hypermobility.

Q. Did you do any testing during your examination to confirm whether she still has urethral hypermobility?

A. Yes, I did.

Q. And what did you do?

A. One of the -- one of the things I do during a pelvic exam when I'm examining the patient is have them bear down or cough to see if that produces any prolapse.

Q. And what did you find when you did that?

A. She did not have any evidence of prolapse.

Q. So does that indicate she had no evidence of urethral hypermobility?

A. That's correct.

Q. So is it your impression that the TVT has worked to improve that condition?

MS. SANTRA: Object to form.

THE WITNESS: It has anatomically corrected the hypermobility in my opinion.

BY MS. ROBINSON:

Q. Where did you report those findings?

A. Well, since those are -- findings were not positive findings, I didn't document the fact that she did not have urethral hypermobility. In fact, when I populate findings on my electronic health resource, in a lot of instances, if, for example, someone doesn't have urethral hypermobility, it won't necessarily add it there.

Some of them -- it'll populate if there's no cystocele or rectocele, for example. It'll say no cystocele, no rectocele. So if you look at my IME, it'll actually populate no

cystocele, no rectocele. It doesn't, however, populate no urethral hypermobility. It only populates that in a positive sense if it's there.

Q. I didn't even really see in your report where you had done a cough stress test.

A. Yes. Like, once again, I do it on every woman who has incontinence as a part of my practice, part of my examination.

If the findings are negative, it's not reflected in my report. It's not reflected in my physical exam because it's --

Q. What other type of negative findings might you have that would not be reflected in this exam note that we have as Exhibit No. 5?

A. Well, for Mrs. Ward, there were two negative findings that weren't -- two positive findings that because they were negative weren't noted.

One was that a lot of times

when I'm doing a pelvic exam, if I appreciate constipation, I'll document that, so she had none of that, no constipation.

And if the bladder is palpable, oftentimes I will document the bladder as being palpable. Her bladder was not palpable.

Q. And what do you mean by the bladder being palpable?

A. That I could palpate it even after emptying, suggesting that perhaps one is not emptying their bladder well.

Q. Okay. So when you examined the bladder, you confirmed essentially the postvoid residual finding that she had normally emptied her bladder?

A. Right.

Q. Is there anything else that didn't show up in your exam report that was a normal finding?

A. None that I can think of here today.

Q. So do I understand correctly

then that based on your exam, she has had an anatomical correction of her urethral hypermobility?

MS. SANTRA: Susan, sorry. Can we take a quick restroom break or do you want him to answer --

MS. ROBINSON: Yeah, let him answer that question first.

THE WITNESS: Could you repeat the question, Susan?

MS. ROBINSON: Let's take a break and we'll have the court reporter read it back then.

THE WITNESS: Fair enough. Thank you.

MS. SANTRA: Thanks. Sorry about that.

(A recess was taken from 10:10 a.m. to 10:16 a.m.)

MS. ROBINSON: And if I can just get the court reporter to read that question back and then we're ready to go.

- - -

(Whereupon, the court reporter read back from the record as follows:

"QUESTION: So do I understand correctly then that based on your exam, she has had an anatomical correction of her urethral hypermobility?")

- - -

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. Doctor, during -- did you visually see any leakage during the cough stress test?

A. I did not, although she had very little in her bladder to leak out, to be fair.

Q. But your objective findings did not demonstrate any recurrence of her stress urinary incontinence; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: Well, unfortunately, they weren't really

designed to demonstrate such, but -- but, no, they did not.

BY MS. ROBINSON:

Q. Well, let me ask the question again, because it's a very straightforward question: Doctor, did your objective findings on your examination of the plaintiff, Mrs. Ward, document a recurrence of her stress urinary incontinence?

MS. SANTRA: Object to form.

THE WITNESS: No, they did not.

BY MS. ROBINSON:

Q. Doctor, what -- assume for a minute that Dr. DeLeary did note that he saw components of overactive bladder and that Mrs. Ward during her deposition testimony said she did have some urge symptoms prior to her TVT placement in 2005. Okay?

A. Okay.

Q. Just assume for me that that's correct.

A. Okay.

Q. Doctor, what would have caused Mrs. Ward to have overactive bladder symptoms prior to her TVT placement?

A. Well, there are a lot of different causes for overactive bladder. So some of it is idiopathic. Sometimes overactive bladder can be attributed to lifestyle issues such as caffeine or bladder irritant intake. There are instances where, for example, constipation, if it's severe, can exacerbate overactive bladder symptoms.

Q. Anything else?

A. Well, weight can sometimes be an exacerbating factor of overactive bladder.

Q. Anything else?

A. None that I can think of as we sit here today.

Q. Do you agree with me that all of those factors exist in Mrs. Ward today?

A. To some degree they do, yes.
Q. Number one, her overactive bladder symptoms could simply just be idiopathic in nature; correct?
MS. SANTRA: Object to form.
THE WITNESS: Possibly.
BY MS. ROBINSON:
Q. Two, her overactive bladder symptoms could be caused by her lifestyle; correct?
MS. SANTRA: Object to form.
THE WITNESS: Possibly.
BY MS. ROBINSON:
Q. Did you see in her deposition testimony that she drinks up to three containers of tea a day?
A. Yes.
Q. Do you agree with me that tea which contains caffeine can be a bladder irritant?
A. Yes.
Q. And that that can cause overactive bladder symptoms?
A. Yes.

Q. Do you also see that she has intake of six to eight glasses of water a day as well?

A. Yes.

Q. And so you agree with me that some of her lifestyle factors today can impact her complaints of overactive bladder; correct?

A. Not necessarily water intake, but some of the other stuff we discussed, yes.

Q. She still complains of intermittent constipation as well; correct?

A. Which she described to me as mild, but yes.

Q. And if you look at your IME, you've documented her current weight today at, I believe it's, 232 pounds?

A. Yes.

Q. And, Doctor, assume for me that one of her visits to Dr. Highland documented that she weighed about 182 pounds before her TVT implant. That

shows about a 50-pound weight gain; is that correct?

A. Yes.

Q. Do you agree with me that her weight gain can affect her urinary functioning?

A. Yes.

Q. Do you agree with me that weight gain can cause her to have urge symptoms?

A. Yes.

Q. Do you agree with me that her weight gain could even cause stress incontinence?

A. Yes, to some degree, that's true.

Q. Do you agree with me that her 50-pound weight gain could make her urge incontinence symptoms worse?

A. Possibly, yes.

Q. Did you recommend to her that she loses weight?

MS. SANTRA: Object to form.

THE WITNESS: Not being her

treating physician, we didn't discuss that.

BY MS. ROBINSON:

Q. But it isn't surprising to you that somebody who might have had some slight overactive bladder symptoms in 2005, if they gain over 50 pounds ten years later, continued to have caffeine intake, it isn't surprising to you that their overactive bladder symptoms could worsen.

MS. SANTRA: Object to form.

THE WITNESS: I mean, in the absence of all the other medical nuances to Mrs. Ward and that this was just a patient who did nothing else other than gain 48 pounds and continue along with her current bladder irritant intake, is that the question?

MS. ROBINSON: Yes.

THE WITNESS: It's plausible, but -- but for Mrs. Ward, it's a little more

complicated than that, because she has obviously mixed urinary incontinence. It's not straight urgency or overactive bladder-related incontinence.

BY MS. ROBINSON:

Q. You also saw that she has been diagnosed within the last few years of having diabetes; is that correct?

A. Yes.

Q. How does diabetes affect voiding?

A. Well, to a certain extent, it depends on the duration of the diabetes and one's hemoglobin A1C, which serves as a fairly good indicator of diabetic control.

So for patients who have long-standing, poorly controlled diabetes, sometimes what we see is actually impaired bladder sensation where the bladder doesn't feel itself to the same degree it did in the nondiabetic state.

Q. And if that's the case, then what impact does it have on somebody's urinary function, their frequency, their overactive bladder symptoms?

A. So, I mean, she's only really had diabetes to my mind for the last three years or so, so I'm not really privy to her hemoglobin A1C levels. To my -- you know, to my discredit, I suppose, I didn't ask her that specific question.

But assuming her hemoglobin A1Cs were in poor control, it could have a -- you know, it could have a minor impact over three years, but nonetheless an impact.

Q. And without -- you do not have sufficient information right now to rule the diabetes out as a potential influence or a potential cause of her overactive bladder symptoms; is that correct?

A. Well, I would put minimal weight on diabetes, but I wouldn't rule

it out entirely.

Q. With regard to her medications, did you review that list with her?

A. Yes.

Q. Was she taking any pain medications for complaints that she had related to the TVT?

(Pause.)

MS. ROBINSON: I'm sorry. Are you there?

THE WITNESS: I'm here. I'm just trying to process the question, because the pain that she was relating to me was pelvic and vaginal pain, including groin pain.

And inasmuch as I was aware of the fact that she was taking multiple pain medications, hydrocodone, for example, meloxicam, for example, my understanding is that she was taking them for pelvic pain, but

she didn't make mention to me that she was taking them for other purposes.

BY MS. ROBINSON:

Q. Well, if I told you she was taking pain medications for her neck and shoulder and back --

A. Uh-hum.

Q. -- would that be inconsistent with your understanding of what she -- what she presented to you?

A. Well, not necessarily, but -- only because I was aware of her having those conditions at the time of my IME.

That being said, I would imagine that those medications, whether they're being used for her back or neck pain, were probably having some impact on her pelvic pain.

Q. Are you testifying that the pelvic pain that she experiences is so severe that she has to take a pain medication like hydrocodone to control them?

MS. SANTRA: Object to form.

THE WITNESS: Well, no, not necessarily.

BY MS. ROBINSON:

Q. You've never seen a medical record, a single medical record, where a doctor has prescribed her with pain medication for any complaints that she has related to the TVT; correct?

MS. SANTRA: Object to form.

THE WITNESS: These pain medications were not prescribed by urologists, gynecologists, or TVT-related doctors.

BY MS. ROBINSON:

Q. And, in fact, she has never complained to a single doctor that she has experienced pain during sexual intercourse; is that correct?

MS. SANTRA: Object to form.

MS. ROBINSON: Other than yourself.

THE WITNESS: No.

BY MS. ROBINSON:

Q. Let me reask the question: Is it correct that, according to your review of your -- of her medical records, that she has never complained to a single one of her treating physicians that she has experienced pain during sexual intercourse?

MS. SANTRA: Object to form.

THE WITNESS: Could you repeat the question? I'm sorry, Susan.

BY MS. ROBINSON:

Q. Doctor, let me try to make it simpler.

A. Okay.

Q. In your review of her medical records, did you find anywhere where she had made a single complaint to any of her treating physicians that she experienced pain during sexual intercourse?

A. No.

Q. Doctor, if you'll turn to page 4 -- well, first, let me -- let me

-- before we do that, let's talk about the review -- or her history of present illness?

Did you find any inconsistencies in her recitation of her history to you with what you later reviewed in the medical records?

A. I'm sorry. I don't know if I understood that question, Susan.

Q. The history of present illness, if I understand correctly, was her providing you with that information during your examination; correct?

A. That's correct.

Q. Did you later find any inconsistencies with what she told you in your review of her medical records?

A. Not especially, no.

Q. Up -- about five lines up, you state: She notes bilateral groin pain, intermittent, dull, sometimes after walking.

A. Yes.

Q. Did you see anywhere in her

medical records that she had made that complaint to any of her treating physicians?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. Where did you see that?

A. As an example, in 2012, she saw Dr. Highland with complaints of left-sided pain, pelvic pain, which is in the same region as the groin.

Q. Does that pain specify that she's having that pain with walking?

A. No.

Q. Did I understand correctly that that is pelvic pain that you related to her ultimate surgery for the hysterectomy?

A. To some degree, yes.

Q. Can you tell me how you did the vaginal exam?

A. Yes. So my patients lie in the prone position. They -- typically I'll examine their abdomen first; and

then when they undergo a pelvic exam, they will either go into a position called the frog leg where they bend their legs in kind of a diamond shape or, in this instance, they'll be positioned in a lithotomy position where their legs are up in stirrups.

At that point, I'll examine them with -- do what's called a bimanual exam, using gloves, whereby I separate the labia to examine their external genitalia, ask them -- first off, assess the rugation or whether or not there's atrophy to the vulvovaginal tissues, examine for discharge, adequate lubrication and such, and then perform what's called a bimanual exam where I'll insert my fingers into the vaginal canal and ask them to bear down or cough to assess if there's any prolapse.

During the bimanual exam, there's also an opportunity for me to palpate certain areas or trigger points to see if there's pain to palpation.

Q. At the time you were doing this examination, you know that she is complaining of having dyspareunia; correct?

A. She had made that complaint to me during her interview, yes.

Q. When you performed the examination, did you use one digit or two?

A. Typically, two.

Q. Did she describe that she experienced any pain when you began the examination just on insertion of the two digits?

A. Prior to my insertion, she had no pain.

Q. At what point did she experience some pain?

A. Typically -- in her instance, her pain was almost exclusively in her anterior urethra, directly along and under the sling, more so on the right side than the left side.

Q. I guess I'm trying to get an

understanding at what point in your examination she would have had any pain.

A. Right. And I guess what I -- maybe my answer wasn't clear before.

So when I placed my fingers inside of her to examine her for prolapse, I also would, you know, palpate the vaginal canal throughout, the floor of the vaginal canal, what's called the apex or the uppermost portion of the vagina and then what's called the anterior vaginal canal underneath the bladder and the urethra.

In her particular instance, in terms of point tenderness and point palpation, she had tenderness underneath the sling in the area of the mid-urethra with more tenderness up on the sidewalls of the vaginal space. In Mrs. Ward's instance, more in the right vaginal sulcus than the left.

Q. And how did she express that tenderness to you?

A. As I recall, that she would

say, yeah, it's right there, it's -- that's where it hurts; and in terms of the differentiator in terms of the quantitative amount of discomfort, it was -- it was more uncomfortable on the right side than the left in the area of the vaginal sulci.

Q. Was it so uncomfortable that she could not endure your examination?

A. It was close to that point. I mean, I didn't really mash the tissues that aggressively, but I did it firmly enough that she elicited -- that it elicited pain.

Q. Did you notice any scarring at the apex?

A. Nothing significant.

Q. Does that mean you didn't notice scarring?

MS. SANTRA: Object to form.

THE WITNESS: Well, once again, I think we're getting into a discussion about documenting a significant negative and whether

or not, I guess, number one, whether my computer would do that for me automatically and whether or not I would add that information.

What I can tell you is, if there was apical scarring, it was insignificant enough that I didn't feel it necessary to put in the report.

If I were to re-examine her today and you were to ask that question and I was to examine her realtime, I would probably have said I can, you know, feel the vaginal cuff scar if I felt it closely enough. But was it a -- an excessive, thick, tender scar? No.

BY MS. ROBINSON:

Q. Other than your notation that she had tenderness under the urethra, did she have -- were there any other abnormal findings during your

examination?

A. Yes. There was -- besides induration, there was also a -- a taut feeling to the sling in those particular areas, where it almost felt as if the edge of the sling felt more sharper and more pronounced.

Q. But do I understand correctly that there was no mesh exposure; correct?

A. That's correct.

Q. You were unable to feel any mesh underneath the scarring; correct?

MS. SANTRA: Object to form.

THE WITNESS: I could palpate the sling underneath the scar tissue, but I could not appreciate, feel, or see any extrusion.

BY MS. ROBINSON:

Q. She's never had any mesh exposure or extrusion; correct?

A. Not to my knowledge, no.

Q. In your medical practice, is

it uncommon for you to be able to feel palpable mesh after a sling has been placed?

MS. SANTRA: Object to form.

THE WITNESS: Somewhat.

BY MS. ROBINSON:

Q. But it is something that you feel in cases; correct?

A. Yeah. If you're trying to identify it and trying to feel it, in most instances, you're able to.

Q. And when -- in those instances, not all of those instances reproduce pain; correct?

A. That's correct.

Q. Is it also true that if you have placed a fascial sling for stress urinary incontinence, that you can feel where that sling has been placed after the surgery?

A. That tends to be much more challenging in my hands, but still possible.

Q. Every surgical procedure for

stress urinary incontinence has a risk of scarring; correct?

A. Yes.

Q. And that risk of scarring can be prevented only by not doing the surgery; correct?

A. Yes.

Q. Can delayed healing increase the scarring during -- after a stress urinary incontinence surgery?

MS. SANTRA: Object to form.

THE WITNESS: I don't know if I understand your question.

BY MS. ROBINSON:

Q. If there is a delay, if for some reason the scar doesn't heal in the ordinary process, can that create an increase in the vaginal scarring?

MS. SANTRA: Object to form; vague.

THE WITNESS: Yeah, I suppose it depends on the cause of the delayed healing, the underlying issue related to that

delayed healing, but that's a plausible theory.

BY MS. ROBINSON:

Q. Did you see in the medical records that a week after her surgery, the plaintiff had a coughing fit and felt pain and experienced bleeding from her vagina after her surgery?

A. Uh-hum.

Q. You did see that; correct?

A. Yes, I did.

Q. Can that be something that would interfere with her normal healing process?

A. Well, you know, taking that as a standalone question, I would say yes, but I think her clinical history would go against that in the instances of that particular situation you're speaking of.

MS. ROBINSON: Okay. Well, move to strike everything after "yes."

MS. SANTRA: Object.

BY MS. ROBINSON:

Q. My follow-up question is, does that indicate to you that there might have been a little ripping or a little tearing?

MS. SANTRA: Object to form.

THE WITNESS: No.

BY MS. ROBINSON:

Q. Is it possible that following that event, that that event could have caused greater type of scarring for her than what otherwise might normally have occurred?

A. I would say no to that.

Q. And what do you base that on?

A. Well, I base that on the lack of anything within the medical records that would indicate that that particular instance where she had this, I guess, coughing spell and subsequent bleeding spell -- there was nothing in her post -- in evaluations following that that indicated that she was having any

sort of delayed healing or significant scarring that would support that theory.

In fact, despite that, she actually had, as we discussed, an initially good result to her sling. So it's just hard for me to imagine that something happening on June 27th, 2005, with a follow-up approximately nine days later on July 6th where the vaginal bleeding had stopped that same day and she had no further problems or pain -- of pain or discomfort, you know, voiding well, denying any leakage, it's hard for me to state that that would have been a risk factor for either delayed healing or excessive scarring or any other complication.

Q. Doctor, during your examination, she had a normal urinalysis; is that correct?

A. Well, with the exception of glycosuria, yes. She had sugar in her urine.

Q. And that's consistent with

her diabetes; correct?

A. Yes.

Q. Is that an abnormal level of sugar?

A. That is.

Q. How high is that?

A. Well, typically, for someone to spill sugar in their urine, their blood sugar has to be over 180. So I can't comment as to the specific blood sugar level, but it's suggestive of the fact that her sugar was not adequately controlled at the time of her visit to me.

Q. Under your assessment and plan, when you talk about pain in pelvis, pelvic and perineal pain --

A. Correct.

Q. Do you see that?

A. Yes.

Q. -- did she experience pain in the perineal area during your examination?

A. No.

Q. Where does that come from?

A. That is an ICD-10 code that unfortunately groups pelvic pain under the nomenclature of pelvic and perineal pain.

Q. So she -- are you saying she did not have any peroneal pain and that's just an electronic entry?

A. Yes, ma'am.

Q. Doctor, I'm still a little confused about the pelvic pain complaints. Are those complaints distinct from the dyspareunia complaint?

A. Yes, they are.

Q. Was there anything on your examination that had -- supported any -- you know, any of her symptoms of pelvic pain other than the dyspareunia?

A. Well, I mean, the pelvic exam, to be fair, didn't demonstrate dyspareunia. It just provoked pain on vaginal exam. So certainly vaginal pain was reproducible. The vaginal pain that was produced on exam was consistent with

where she had had dyspareunia.

But regarding pelvic pain, it really only was borne out during my interview with the patient. I wasn't able to re-create, for example, groin pain on examination.

MS. SANTRA: Off the record.

- - -

(A discussion off the record occurred.)

- - -

BY MS. ROBINSON:

Q. Doctor, I think you were describing during your examination you were not able to reproduce any groin pain; is that correct?

A. That's correct.

Q. And with regard to pelvic pain itself, did I understand correctly on what you were saying that while your examination showed some tenderness, that isn't necessarily indicative of somebody in her daily activities experiencing pelvic pain?

A. To some degree. So, for example, my physical exam demonstrated some of the pelvic pain that Mrs. Ward had, but not all that was described to me, and I'm not convinced that the pain she has at rest that's worsened by walking is necessarily the vaginal pain that I reproduced on exam.

Q. Are you testifying to a reasonable degree of medical certainty that the pain that she describes upon walking is caused by the TVT?

A. I wouldn't attribute it solely to the sling, no.

Q. And what's the basis that you attribute it partially to the sling?

A. Well, the placement of the sling is -- is in the area of her pain, so I wouldn't rule it out because of that.

Q. Would you agree with me the literature does not support incidences of groin pain following TVT surgery?

MS. SANTRA: Object to form.

THE WITNESS: Well, I don't know if I would necessarily agree with that, because I think it also depends on the route of placement. I mean, in other words, a TVT Obturator sling has a higher risk of groin pain than a retropubic TVT sling, for example.

BY MS. ROBINSON:

Q. And she has the retropubic; correct?

A. That's correct, yes.

Q. With regard to her dyspareunia, what does your examination tell you -- or how does your examination play in your assessment that her dyspareunia is caused by the TVT?

A. Well, it's a combination both of her subjective complaints and objectively what I discovered. To be fair, she had only had sex with her husband about three or four times and, in fact, hadn't been sexually active after her hysterectomy, but she describes

specifically that the pain being pain in the vaginal canal and in the groin area.

Taking her groin pain out of the equation relating to her dyspareunia, when I examined her, the pain that I was able to reproduce on exam corroborated with the physical location of the pain that she had during intimacy, and when I say the pain in her vaginal canal is what I'm speaking towards.

Q. And how did it corroborate? Did it corroborate in terms of location? Did it corroborate in terms of intensity?

A. Probably more location, you know, than intensity; and, I mean, I don't want to sound graphic here, but it's difficult to reproduce, you know, vaginal intercourse-related pain during a bimanual exam obviously.

Q. Okay.

So then how do you know that the location is consistent with the pain she would experience during sexual intercourse?

A. So, I mean, to the point of dyspareunia or vaginal pain, I guess there are two elements. One is that -- the quality of the pain and the other is the location, I suppose. And the quality can have its own breakdown I guess as to particular elements.

But when I was examining Mrs. Ward, for example, and reproducing tenderness on exam, she recounted to me that the pain that she was having during my vaginal exam was the same location-wise as the pain she had during intimacy, during intercourse.

Q. So it's based on her telling you that when you touched her in a certain area, that was the area she was having pain during sexual intercourse.

A. It may have been the other way around. It may have been more me examining her and eliciting tenderness and saying, is this where you were having pain when having sex, when having intercourse, to which she recounted yes.

Q. Did you take any measures to account for the fact that she's in litigation?

MS. SANTRA: Object to form.

THE WITNESS: I did not.

BY MS. ROBINSON:

Q. And you understand that pain is pretty much subjective. Right?

MS. SANTRA: Object to form.

THE WITNESS: I mean, I think pain has certainly different layers of quality and significance.

BY MS. ROBINSON:

Q. Did you find anything during the course of your examination that you felt would prevent her from having sexual intercourse?

MS. SANTRA: Object to form.

THE WITNESS: Well, I think the term "prevent," it probably has multiple layers, too. Are you speaking about kind of mechanically?

MS. ROBINSON: Yes.

MS. SANTRA: Object to form.

THE WITNESS: I mean, with the exception of the scar tissue and the tenderness to it around the area of her sling, no.

BY MS. ROBINSON:

Q. Speaking specifically about the scar tissue and the tenderness, are you able to testify that that in and of itself is significant enough to prevent sexual intercourse?

A. Well, this is one of these areas where we have to kind of jump from one particular arena to the other.

So I'm understanding through an interview and exam with this patient that it's painful, so kind of the pre-answer premise to your question is that intimacy is so painful for her that she doesn't want to have it.

That being said, could an average-sized -- not to be graphic, but an average-sized penis be inserted into

her vagina? I would say the answer to that would be yes.

Q. You have treated -- well, have you treated patients who come to you and do not have sex because they have pain during sexual intercourse?

A. Yes.

Q. And is it fair to say that many of those patients have never had a TVT sling placed?

MS. SANTRA: Object to form.

THE WITNESS: Some of them, yes.

BY MS. ROBINSON:

Q. Is it fair to say that, you know -- well, I'm not talking about the TVT sling. I'm talking about any sling.

A. Right.

Q. Okay.

And in those instances, are they there so that you can help them have more comfortable sexual intercourse?

A. Yes.

Q. And what is it that you

recommend that they do?

A. Well, it depends on what's causing the dyspareunia.

Q. And there are many different potential causes of dyspareunia; correct?

A. There are -- there are multiple causes.

Q. And, for example, can you tell me that on the one or two occasions that Mrs. Ward had attempted sexual intercourse with her husband, that her pain was not caused by either her -- the ovarian cyst she had or the endometrial problems that she has?

MS. SANTRA: Object to form.

THE WITNESS: Well, I can speak to you about my discussions with her and what she recounted to me.

MS. ROBINSON: Well -- okay. Go ahead and do that.

THE WITNESS: So it was a number -- it was a number -- she had sex about three or four times.

She described the pain as being in both the vaginal canal and in the groins; but when she described it based on her husband's experience, she felt like he was placing a rough stick inside of her with more pain on the right than the left.

BY MS. ROBINSON:

Q. Do you know whether that was consistent with her deposition testimony or not?

A. I don't specifically recall location language in her deposition. I'd have to re-look at it again to see.

MS. ROBINSON: Okay. We'll move on.

Can I get an idea of how much time I have on the record left?

- - -

(A discussion off the record occurred.)

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THE COURT REPORTER: Eight minutes left.

MS. ROBINSON: So I will stop here at 11:10. Okay. So, Doctor, let me move on a little bit.

BY MS. ROBINSON:

Q. On page 2 of your report, which is Exhibit 2, you list a number of common complications with TVT; is that correct?

A. Yes.

Q. Do we agree that you are not relating pain into her legs or thighs to the TVT; correct?

A. Correct.

Q. Do we agree that she does not have chronic inflammation of her tissue?

A. I would disagree with that.

Q. You didn't perform a biopsy. Right?

A. I did not.

Q. She never had her mesh

explanted; correct?

A. That's correct.

Q. Did you visualize any discharge from her vagina during your examination?

A. I did not.

Q. Did you visualize -- did you use a speculum during your examination?

A. I did.

Q. Did you visualize any redness or inflamed areas around her urethra?

A. I did not.

Q. Doctor, you didn't find any scar bands; correct?

A. I did not.

Q. There was no vaginal shortening or stenosis; correct?

A. Not that I identified, no.

Q. There was no erosion or exposure or protrusion of her mesh; is that correct?

A. No, ma'am.

Q. You did not find any nerve

entrapment; correct?

A. No.

Q. There was no roping or curling of her mesh; is that correct?

A. No.

Q. There was no fraying; correct?

A. That's correct.

Q. There was no particle loss that you found; correct?

A. None that I could identify, no.

Q. There was no infection of her wound or infection of the site of her mesh; correct?

A. No.

Q. Do you know if her TVT was mechanically cut or laser cut mesh?

A. I do not know.

Q. As a result of that, is it fair for me to say, Doctor, you cannot attribute any of her injuries to the fact that her mesh was either one or the other?

MS. SANTRA: Object to form.

THE WITNESS: That's correct.

BY MS. ROBINSON:

Q. And there was no degradation of her mesh. Do we agree with that?

A. None that I could identify.

Q. Doctor, with regard to your general opinions regarding the IFU, you've never written an IFU; is that correct?

A. I have not.

Q. You've never worked for a device company and been asked to write their IFU; correct?

A. Only read them, not write them.

Q. You've only -- you've never worked for FDA and been asked to review IFUs; correct?

A. I've not.

Q. Do you know of any regulation with regard to what is required by a manufacturer when drafting

and finalizing an IFU?

A. No.

Q. You are citing to an AMA informed consent requirement and that's 8.08; is that correct?

A. Yes.

Q. And what does that relate to generally?

A. That's a policy regarding informed consent.

Q. Does that require doctors and physicians to give informed consent to their patients?

A. Correct.

Q. That's not a regulation that is placed upon manufacturers; correct?

A. Well, no, not directly.

Q. And you agree with me that the doctor is required to inform the patient; correct?

A. Correct.

Q. You've read Dr. DeLeary's transcript; correct?

A. I did.

Q. And you know that he states that he was aware that dyspareunia was a potential risk at the time he implanted the TVT; correct?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. He was aware that scarring could be a part of that; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. He was aware that voiding dysfunction could occur; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. He was aware that those conditions could be mild, severe; correct?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MS. ROBINSON:

Q. That they could be short

term or long term; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: Correct.

BY MS. ROBINSON:

Q. Doctor, with regard to your testimony about the mesh contracture, can you testify to a reasonable degree of medical certainty having not seen her mesh that it -- that the mesh itself actually contracted?

A. Yes.

Q. And what's that based on?

A. Well, it's based primarily on my physical exam findings, which indicated some tautness and tightness to the area where the sling was located.

Q. And that makes you think that the mesh itself contracted or simply that there was wound contracture?

A. Well, really, typically, it's a combination of both.

Q. Can you tell me what degree it contracted?

A. Well, that's very difficult

to do in the absence of histological or electron micrograph-type specimens.

Q. When did you last implant a polypropylene mesh?

A. About three weeks ago.

Q. If that patient develops dyspareunia in the future, do you believe it's caused by a defect in the mesh?

MS. SANTRA: Object to form.

THE WITNESS: Well, I think that's a difficult question to answer because I think to some degree it depends on, number one, which kind of mesh and, secondly, it would depend to some degree on why the patient is having the dyspareunia; in other words, is it something I would attribute to, in this example, the sling or something else.

BY MS. ROBINSON:

Q. Well, let's back up for a second then and let's say the type of mesh that you currently use is a type 1

lightweight macroporous mesh; correct?

A. Yes.

Q. And TVT is a type 1 lightweight macroporous mesh; correct?

A. Yes.

Q. Have you ever sat down to compare those two types of meshes side to side?

A. Only holding them in my hand type comparisons, not more sophisticated comparisons.

Q. You've never studied them. Right?

A. Not in depth like a molecular or biomechanical type of person might, no.

Q. And --

MS. SANTRA: I think time is up, Susan.

BY MS. ROBINSON:

Q. You're not testifying that that mesh is an alternative to the TVT mesh; is that correct?

MS. SANTRA: I'm going to

instruct him not to answer the question because time is up.

MS. ROBINSON: All right. Go ahead.

MS. SANTRA: I actually need just a two-minute break, if that's all right, so we're going to go off the record for a minute.

(A recess was taken from 11:11 a.m. until 11:15 a.m.)

- - -

EXAMINATION

- - -

BY MS. SANTRA:

Q. Dr. Walmsley, you performed a differential diagnosis when coming to your opinions about Ms. Ward; is that correct?

A. Yes, ma'am.

Q. And when you were performing your differential diagnosis, did you take into account her other medical conditions?

A. Yes, I did.

Q. And I'll just -- I have a list, but did you take into account her past -- or history of infertility, kidney stones, [redacted], migraines, lumbar back pain, abdominal pain, hiatal hernia, constipation, and weight gain of about 48 pounds when you were performing your differential diagnosis on Ms. Ward?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. And considering all her -- all of those other medical conditions, did you still come to the conclusion that the TVT was a cause for her pelvic pain and dyspareunia?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. And did you still come to the conclusion to a reasonable degree of

medical certainty that her TVT was a cause for her urinary dysfunction?

A. Yes.

Q. And when you were performing your differential diagnosis for Ms. Ward, did you take into account her surgical history?

A. I did.

Q. And that included a hysterectomy in 1991, kidney stones in 1996, cholecystectomy, a D & C in 2006 --

MS. ROBINSON: Object to the form.

BY MS. SANTRA:

Q. -- and a -- I'm sorry. Strike that. Let me start over with that.

Ms. Ward's surgical history included kidney stones, a cholecystectomy, a D & C, and a laparoscopically assisted vaginal hysterectomy with BSO; is that correct?

A. Correct.

Q. And did you take into

account her entire surgical history when you performed your differential diagnosis?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. And did you still come to the conclusion that the TVT mesh was a cause for her injuries today?

A. Yes.

MS. ROBINSON: Object to form. I'm sorry. I don't mean to -- Hayleigh, I don't mean to get you off track. I'm just having a hard time getting my objection in before the doctor speaks.

MS. SANTRA: Sure. That's fine.

BY MS. SANTRA:

Q. I want to go to your opinion concerning the IFU. I think that's your general opinion number 1; correct?

A. Yes.

Q. And what is your experience with IFUs?

A. I use IFUs in gaining experience about medical devices and procedures relating to those devices. I rely upon it to help me not only guide me technically with the procedure, but allow me to understand the indications, contraindications, and potential complications relating to the use of the medical device.

Q. And so does your opinion on the TVT's IFU as of 2005 come from your experience with IFUs as a practicing urologist who relies on IFUs for medical devices --

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. -- every day in your practice or regularly in your practice?

A. Yes.

Q. And early on in the deposition, counsel was asking you what

you knew as far as complications from the TVT in 2005. Do you remember those questions?

A. Yes.

Q. And can you explain your opinion as to why you think the warnings or the adverse reactions that were put in the IFU in 2005 were inadequate to inform doctors about the true risks of the TVT?

A. Certainly. I think the first is in the types, quantitatively the different types, of adverse reactions that can be expected, number one. And then, number two, the nature, significance, chronicity, and/or severity of those adverse reactions as it relates to the fact that some of them are specifically mesh related.

Q. And so in 2005, if someone understood that there may have been a possibility for pain with the TVT implant, does their understanding as to the nature and chronicity and character of that pain matter? Does that make

sense?

A. Yes.

MS. ROBINSON: Object to form.

THE WITNESS: Yes, and to that end, having pelvic pain after any incontinence procedure, yes, that's an expectation. That being said, when using synthetic mesh as a means of performing that antiincontinence procedure, the pelvic pain that is inherently related to the mesh is actually quite different from the pelvic pain one might expect from, let's say, a nonmesh-related antiincontinence surgery.

So I think that for an antiincontinence surgery to read about pelvic pain from a mid-urethral sling, for example, he or she may be drawing a conclusion that, oh, well, this is the typical kind of pain that I

would expect after, let's say, an autologous fascial sling procedure or a Burch procedure, where in fact it's different simply because the kind of pain that mesh can induce is different.

BY MS. SANTRA:

Q. And we were talking about your examination of Ms. Ward in that you said if you were treating her as a treating physician, you may order a urodynamic study if you were to see her again; is that right?

A. I would consider it, yes.

Q. Could you treat Ms. Ward without doing a urodynamic study if she was your patient?

A. Yeah, I probably would, in fact, treat her in anticipation or before a urodynamic study.

Q. And so even without doing that urodynamic study, you're confident that you have enough information to render your opinions about Ms. Ward to a

reasonable degree of medical certainty?

A. That's correct.

Q. And you also had talked about the fact that you performed a cough stress test of Ms. Ward; is that correct?

A. I did, albeit not typically, because typically, a cough stress test is done when the bladder's full. In the instance of Mrs. Ward, I was doing the cough stress test primarily to see if there was any urethral hypermobility.

Because her bladder only had 15 cc's in it, even if she really did have genuine stress incontinence, it might be harder to elicit incontinence with a patient lying down on her back with not much urine within her bladder.

Q. So the fact that she did -- she had a negative cough stress test on a day that she went to see you when she didn't have a lot of urine in her bladder, that does not mean that she has no recurrent stress urinary incontinence; is that correct?

A. That's correct.

Q. When you were performing your differential diagnosis of Ms. Ward's overactive bladder, did you consider other factors such as her caffeine intake, her weight, her lifestyle, the fact that it could be idiopathic, the fact that she has a history of constipation, and her diabetes?

A. I did.

Q. And did you still conclude that the TVT is a cause of her overactive bladder symptoms?

MS. ROBINSON: Object to form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And how do you know that or how did you rule the TVT in?

A. Well, in large part, because that the complaints of her voiding dysfunction occurred in a temporal fashion, consistent with TVT-related issues.

For example, the TVT undergoes a shrinkage and a contraction. That in part is the mesh; that in part is wound contraction. And that over time, the fact that she went from actually having benefit from the TVT as far as voiding dysfunction to then developing significant voiding dysfunction certainly is very supportive of the TVT as being a causative factor.

I wouldn't, to the points made earlier, rule out other issues. For example, the fact that she's gained weight would certainly contribute to that, less likely the constipation which she had both before and after her surgeries. And the diabetes, I wouldn't weight necessarily as heavily only because it's only been ongoing for several years.

So I wouldn't necessarily rule out other causes entirely as contributing to her voiding dysfunction, but certainly from a time course

standpoint and clinically, based on the kind of incontinence she has, which is mixed incontinence, which is typically the kind of voiding dysfunction one can see as a complication of TVT, it's certainly a cause.

Q. And in your differential diagnosis for Ms. Ward's pelvic pain, did you consider her history of constipation, endometritis, ovarian cysts, and her other surgeries?

A. Yes.

Q. And you still came to the conclusion that the TVT is a cause for her pelvic pain?

A. Correct.

Q. And -- and specifically about the endometritis, you said you couldn't rule it out up until she had a hysterectomy?

A. Correct.

Q. Can you explain that?

A. So there's no evidence of her having any aberrant endometrial

tissue outside of her cervix, uterus, and fallopian tubes, and ovaries for that matter. As a result, and moreover, she had her -- after her hysterectomy, her pelvic pain was no better or no worse.

So it leads me to conclude that, first off, there's no endometrial tissue remaining to cause any sort of endometritis-related pain, number one, and, number two, the fact that her surgery really had no impact on it suggests to me that the surgery itself was not -- the hysterectomy, that is -- a causative factor as it relates to her pelvic pain.

Q. And your examination and interview of Ms. Ward, did you conduct those the same way you would conduct them for any patient who's coming into your office?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. And so the fact that the litigation is ongoing had no effect on your -- your examination or interview or the way you conducted those; is that correct?

A. That's correct.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. Regarding your pelvic exam of Ms. Ward, you reproduced Ms. Ward's pain on pelvic exam with your two fingers; is that correct?

A. Correct.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. Would the activity during sex of the husband's penis be, for lack of a better word, would that be more vigorous or -- than your exam?

A. Yes.

MS. ROBINSON: Object to form.

THE WITNESS: I would think so, yes.

BY MS. SANTRA:

Q. And so from the fact that upon your exam with your two fingers Ms. Ward had pain in the -- in the vaginal sulci, does that lead you to conclude that she would also have that pain upon intercourse?

MS. ROBINSON: Object to form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And can you say that to a reasonable degree of medical certainty?

A. I can.

Q. Going to your case-specific opinions, you mention two things, scar plate and contraction/shrinkage as it relates to Ms. Ward.

First, how do you know that a scar plate formed with Ms. Ward's TVT?

A. Based on my physical examination and the fact that when I

examined her, she had indurating tissue around and extending up to the vaginal sulci where her sling was located. That was the scar plate that I discuss in my report.

Q. And then what evidence did you find that there was contraction or shrinkage of Ms. Ward's TVT?

A. So that was based on the appreciation of the sling in certain areas feeling taut or tense to my palpation.

Once again, that is a shrinkage that I attribute both to the mesh itself contracting, but also to there being some degree of wound contraction as well.

Q. And this -- the scar plate and shrinkage and contraction of the TVT is what is contributing to Ms. Ward's pelvic pain and dyspareunia; is that right?

A. Correct.

MS. ROBINSON: Object to

form.

BY MS. SANTRA:

Q. And does the scar plate formation and the contraction or shrinkage of the TVT also contributing to Ms. Ward's urinary issues?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. Counsel asked you earlier about whether there was chronic inflammation. Do you remember that question?

A. I do.

Q. How do you know that Ms. Ward has chronic inflammation of her tissue?

A. Well, I think, to be fair, the best way to demonstrate that would be to literally remove the mesh and examine it pathologically, during which time, if there were chronic inflammation, you'd see that identified. You'd see a foreign

body response to the mesh-based material.

So my conclusion that there's chronic inflammation is based on my physical exam and the fact that there is a scar plate that is present that continues to be tender on examination, which to me is consistent with a chronic inflammatory process.

Q. And are you basing that on your clinical experience in treating women like Ms. Ward and your knowledge of the medical literature?

A. Yes.

MS. ROBINSON: Object to form.

BY MS. SANTRA:

Q. Counsel asked you whether the TVT was a cause for or contributing to Ms. Ward's UTIs. Do you remember that?

A. I do.

Q. And I think you said you think it is a cause for her UTIs. Can you explain that?

MS. ROBINSON: Wait. I'm going to object to this. I'm going to object to this being outside the scope of his opinions he's rendered in his report --

MS. SANTRA: Well, if he --

MS. ROBINSON: -- on Mrs. Ward.

I mean, nowhere in the four corners of his report does he relate UTIs to her TVT as being a potential injury she sustained as a result of the TVT. And I'm going to object. It's outside the scope and we are limiting him to the four corners of his report.

MS. SANTRA: On the last page of his report, he specifically reserves the right to supplement and amend his opinions, and the point of this deposition is to -- is to clarify and explore his opinions as to Ms. Ward.

If you don't want to

question him on it, that's fine, but I would like for him to state his opinion as to her UTIs on the record.

MS. ROBINSON: I absolutely and totally disagree with that. If he wants to supplement his opinions, he can do it with a supplemental report, which we will then take to the court and state it's out of bounds.

There is no new information that he has that calls for any supplementation of his opinions. He had all of the information necessary to render a full report at the time he filed the report and I object to you trying to expand the scope of his opinions during this deposition during your direct examination.

MS. SANTRA: He's gotten new medical records and new depositions have been taken since

the reporting of his report on July 8th so --

MS. ROBINSON: If you look at his report as it is written, he has documented on the occasions where he has reported UTIs. He has sufficient information. He could have rendered that opinion before.

And I'm not -- I mean, I absolutely object to you exploring this area with him. It is outside the scope of his report and I object to any attempt at this deposition to expand his opinions.

MS. SANTRA: Well, we may issue a supplemental report, and I guess we'll leave the deposition open if you all want to depose him on that.

MS. ROBINSON: We'll just have to take that up later, but I was not prepared to depose him on that because it's not part of his

opinions.

MS. SANTRA: I'm going to move on.

BY MS. SANTRA:

Q. On your reliance list, you have included the materials in and reviewed for the TVT general causation reports; is that right?

A. Yes.

Q. And you have also relied on the TVT general causation report issued in this case just in general as background for your case-specific opinions in this case; is that correct?

A. Yes.

Q. And isn't it true that Ethicon puts in their 2015 instructions for use for the TVT that the TVT can cause acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area?

MS. ROBINSON: Object to form.

THE WITNESS: That's

correct.

BY MS. SANTRA:

Q. And that the TVT can cause pain with intercourse that may not resolve?

MS. ROBINSON: Object to form.

THE WITNESS: That's correct.

BY MS. SANTRA:

Q. And that the TVT can cause acute and/or chronic pain?

MS. ROBINSON: Object to form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And that the TVT can cause voiding dysfunction.

MS. ROBINSON: Object to form.

THE WITNESS: Yes.

MS. SANTRA: I think that's all I have for you. Thank you, Doctor.

THE WITNESS: Thank you.

MS. ROBINSON: Thank you, Doctor.

THE WITNESS: Thank you.

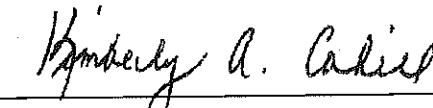
(Witness excused.)

(Deposition concluded at approximately 11:42 a.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, KONSTANTIN WALMSLEY, M.D., have the opportunity to read and sign the deposition transcript.



KIMBERLY A. CAHILL, a
Federally Approved Registered
Merit Reporter and Notary Public
Dated: August 15, 2016

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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PAGE	LINE	CHANGE

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 146, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

KONSTANTIN WALMSLEY, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

PAGE	LINE	